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| EXAMINER | |
|---|---|
| RALIS, STEPHEN J | |

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| 3742 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | |
|---|---|---|
| ***Office Action Summary*** | **Application No.**<br>10/684,124 | **Applicant(s)**<br>BURBANK ET AL. |
| | **Examiner**<br>STEPHEN J. RALIS | **Art Unit**<br>3742 |

***-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 September 2010*.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *68,69,71,73-86 and 111-116* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *68,69,71,73-86 and 111-116* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on *10 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Applicant is respectfully requested to provide a location within the disclosure to support any further amendments to the claims due to when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP § 714.02 and § 2163.06 ("Applicant should specifically point out the support for any amendments made to the disclosure.").

## *Response to Amendment/Arguments*

3. Applicant's arguments filed 15 September 2010 have been fully considered but they are not persuasive as set forth below.

## *Terminal Disclaimer*

4. The terminal disclaimer filed on 15 September 2010 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 7,651,505 has been reviewed and is accepted. The terminal disclaimer has been recorded.

## *Drawings*

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the plunger which is slidably disposed in part within the inner lumen of the delivery cannula proximal to the at

least one solid marker body and detached from the at least one solid marker body must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

## ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 68, 69, 71, 73-86 and 111-116 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant application, the examiner can find no original disclosure to “a plunger which is slidably disposed in part within the inner lumen of the delivery cannula proximal to the at least one solid marker body and detached from the at least one solid marker body”, specifically the recitation to "a plunger… detached from the at least one solid marker body”.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 68, 69, 71, 73-86 and 111-116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 114 recites the limitation “a plunger… detached from the at least one solid marker body”. It is unclear and indefinite to how the plunger can be detached from the at least one solid marker body when the plunger is pushing out the at least one solid marker body. Further clarification is required.

## ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 68, 69, 71, 73-86 and 111-116 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 58, 59, 61-71, 73-77 and 79-89 of copending Application No. 11/342,011. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application claims would be obvious variants to one of ordinary skill in the art based on engineering expediency of the patented claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 68, 69, 71, 73-86 and 111-116 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 58-60, 62-65, 67, 68, 72-77 and 86-93 of copending Application No. 11/342,011. Although

the conflicting claims are not identical, they are not patentably distinct from each other because the instant application claims would be obvious variants to one of ordinary skill in the art based on engineering expediency of the patented claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 68, 69, 71, 113, 114 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al. (U.S. Patent No. 6,228,055) in view of Voegele et al. (U.S. Patent No. 6,261,302) and Fulton, III et al. (U.S. Patent No. 6,270,464).

Foerster et al. disclose, in Figures 12-15, a delivery cannula defined at least in part by an inner wall surface (inner surface of tube 54b) for implanting biopsy site markers that ejects biopsy markers (column 10, lines 5-12; column 12, lines 6-8; see Figures 12-15) from the cannula into the desired tissue without the need to push the distal end of the cannula out from the lateral biopsy window. In addition, Foerster et al. disclose a plunger (mandrel 98e) which is slidable in the inner lumen (see Figure 15) proximal to at least one solid marker body and detached from the at least one solid marker body (12e). Such a feature utilizes compressive forces rather than tensile forces for delivery (column 10, lines 5-12). Moreover, as noted in column 10, lines 5-11 and column 13, lines 16-29, the device can eject multiple markers individually in series with Figure 15 disclosing 5 markers.

Foerster et al. disclose all of the limitations of the claimed invention, as previously set forth, except for a ramp within the cannula inclined to the elongated discharge port and the plunger urging the plurality of marker bodies into engagement with the ramp and slidably move the plurality of marker bodies up the ramp and out of the discharge port in the delivery cannula into the biopsy cavity; and the plurality of marker bodies being formed of a bioabsorbable material (i.e. gelatin or collagen); at least one body being ultrasonically detectable and at least one other of the marker bodies being radiographically detectable; the marker body being solid at a temperature of 40º C; at least one marker body having a colorant incorporated therein.

However, a ramp within the cannula of a biopsy marker delivery tool configured to urge a marker body out of the discharge port into the biopsy cavity, as described by Voegele et al., is known in the art. Voegele et al., for example, teach an applier (30) for delivering and deploying a biopsy marker to a biopsy site. In addition, Voegele et al. teach the applier (30) comprising an egress tube (63) having an egress opening (64) further having an egress ramp (65) (column 8, line 65 – column 9, line 2; see Figures 1, 2, 5, 7, 8, 13, 17, 18, 19). Voegele et al. further teach the advantage of such a configuration provides for proper delivery and placement at the biopsy site (column 9, line 63 – column 10, line 4; see Figures 20-28). Furthermore it is noted that such a configuration provides that ability to eject the marker cannula for implantation in the tissue in a direction substantially perpendicular to the longitudinal movement of the ejector, thereby increasing the accuracy and placement of the marker into the biopsy site.

Similarly, Fulton, III et al. teach a biopsy site marker (34) from a dehydrated collagen (dehydrated being solid) so that the marker swells and softens in its post-delivery state following delivery from delivery device (32) (see (1) column 5, lines 3-21, (2) column 6, lines 47-50, and (3) Figure 5). In addition to its visual detectability via a coloring agent (column 3, lines 53-54), the marker is also ultrasonically and radiographically detectable (column 3, lines 56-59). Furthermore, Fulton, III et al. note in column 6, lines 57-63 that a gelatin (line 63) may be substituted for the collagen material.

Fulton, III et al. teach, as noted above, a single marker being ultrasonically and radiographically detectable (column 3, lines 56-59). Fulton, III et al. also disclose that the change in the bioabsorbable element can occur via one of several ways (column 3, lines 45-50). Fulton, III et al. further disclose that the invention may employ one or more of these techniques or measures. For instance, *Fulton, III et al. disclose "the palpable marker may be inserted into the suspicious area of the breast under mammographic or ultrasonic guidance"* (column 2, lines 47-50; column 3, lines 15-18). Fulton, III et al. clearly teach a single element that has mammographic or ultrasonic guidance functionality, thereby inherently having the ability to function with both radiographical and ultrasonic equipment. In addition, Fulton, III et al. explicitly teach a single bioabsorbable element (34) that *may be* visually enhanced, radiographically enhanced and ultrasonically enhanced (column 3, lines 45-59). There is no disclosure that the single bioabsorbable element can only be enhanced by a single enhancement. In that regard, Fulton, III et al. teach "***the remotely visualizing step is carried out by at least a chosen one of ultrasound, MRI and mammography***" (page 9, claim 31). Since Fulton, III et al. explicitly teach that one or more techniques may be employed for measurement, and visual detectability, radiographic detectability, and ultrasonic detectability being separate measurements of the element, the bioabsorbable element may inherently employ both radiographic detectability and ultrasonic detectability. Therefore, Fulton, III et al. fully meets “wherein at least one marker body is being ultrasonically detectable and at least one other of the marker bodies being radiographically detectable” given its broadest reasonable interpretation.

Fulton, III et al. also teach the advantage of such a configuration provides a means to permits the biopsy site to be relocated by palpitation to eliminate the need to use metallic clips during biopsies and often eliminates the need for return to the radiologist for pre-operative localization.

In view of Voegele et al., it would have been obvious to one of ordinary skill in the art at the time of the invention was made to provide a ramp within the cannula inclined to a distal portion of the elongated discharge port and urge a marker body out of the discharge port into the biopsy cavity to allow for proper delivery and placement at the biopsy site and to provide a ramp within the cannula inclined to a distal portion of the elongated discharge port and urge a marker body out of the discharge port into the biopsy cavity and to provide a mechanism to eject the marker cannula for implantation in the tissue in a direction substantially perpendicular to the longitudinal movement of the ejector, thereby increasing the accuracy and placement of the marker into the biopsy site. Similarly, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the plurality of marker bodies of Foerster et al. with the bioabsorbable bodies of Fulton, III et al. in order to provide a means to permits the biopsy site to be relocated by palpitation to eliminate the need to use metallic clips during biopsies and often eliminates the need for return to the radiologist for pre-operative localization. Furthermore, to the degree it can be argued that the combination does not teach a plurality of markers which has one which is ultrasonically detectable and another is radiographically detected, to provide a plurality of markers which has one which is ultrasonically detectable and another is radiographically detected would have been a mere engineering expediency as Fulton, III et al. clearly teach the use of a single marker being ultrasonically and radiographically detectable (column 3, lines 56-59) as well as a single bioabsorbable element (34) that *may be* visually enhanced, radiographically enhanced and ultrasonically enhanced (column 3, lines 13-18) and Foerster et al. teach the use of a plurality of separate markers being used for marking a biopsy site in a single application.

Regarding claim 69, the cited prior art does not expressly disclose the body's ability to remain solid at 40º C. However, not only is such a feature implied by the prior art to ensure the marker remained intact after implantation (i.e., upon exposure to body temperature), the skilled artisan would know to select such a body because the marker is intended to be implanted into the patient and therefore must remain solid at temperatures several degrees above body temperature. Therefore, it would have been obvious to one of ordinary skill in the art to provide a body that is solid at 40º C in the previously described apparatus to ensure the marker remained intact after implantation.

17. Claims 73-75, 85 and 86 (as best understood) are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al. (U.S. Patent No. 6,228,055) in view of Voegele et al. (U.S. Patent No. 6,261,302) and Fulton, III et al. (U.S. Patent No.

6,270,464) as applied to claims 68, 69, 71, 113, 114 and 116 above, and further in view of Sirimanne et al. (U.S. Patent No. 6,356,752).

Foerster et al. in view of Voegele et al. and Fulton, III et al. discloses all of the claimed limitations, as previously set forth, except for the radiographically detectable marker body having a radiopaque member; the radiopaque member being disposed with the marker body; the radiopaque member having a loop and least one free end; the radiopaque member being formed of a material selected from a group consisting of titanium; stainless steel, tantalum, gold, platinum and palladium; and the radiopaque member being formed at least in part of titanium.

However, a radiographically detectable marker having a radiopaque member that may be disposed inside of the marker body having a loop and at least one free end and being made of a material selected from a group consisting of titanium; stainless steel, tantalum, gold, platinum and palladium is known in the art. Sirimanne et al., for example, teach a bioabsorbable body (104) containing a radiopaque member (150, 154; see Figures 1A-1D, 1F, 2A-2F, 3C, 3D) in which the radiopaque member may be made of a material made of selected from a group consisting of titanium; stainless steel, tantalum, gold, platinum and palladium (column 9, lines 29-43). Sirimanne et al. further teach the advantage of such a configuration provides a means to aid a physician to determine the spatial orientation of the deployed device. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the radiographically bioabsorbable marker body of Foerster et al. in view of Fulton, III et al. with the radiopaque marker therein of Sirimanne et al. in order to provide a means to aid a physician to determine the spatial orientation of the deployed device, thereby increasing the operational efficiency of the marker bodies.

18. Claims 76-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al. (U.S. Patent No. 6,228,055) in view of Voegele et al. (U.S. Patent No. 6,261,302) and Fulton, III et al. (U.S. Patent No. 6,270,464) as applied to claims 68, 69, 71, 113, 114 and 116 above, and further in view of Yamamoto (U.S. Patent No. 4,847,049), as evidenced by Ronan et al. (U.S. Patent No. 5,820,918).

Foerster et al. in view of Voegele et al. and Fulton, III et al. discloses all of the claimed limitations, as previously set forth, except for specifically calling for at least one of the bodies being formed of a cross-linked bioabsorbable material and having a radiographically detectable metallic ion bound to the cross-linked bioabsorbable material.

However, binding metallic ions to collagens in medical devices used in contact with bodily fluids and tissues is well known in the art to protect against bacterial and fungal attack. Yamamoto, for example, discloses contacting a renatured, cross-linked collagen with silver ion-containing solution with a PH from 4.0-9.0 to cause silver ions to be chelated to functional groups in the renatured collagen. The silver-chelated collagen is then exposed to UV radiation at a 210-310 nm wavelength for 5-15 minutes (column 4, lines 23-24) to strengthen the binding of the silver ions to the renatured collagen (column 2, lines 7-19 and 60-68). Yamamoto further teaches the use of renatured collagen instead of naturally occurring collagen to provide a collagen material that is less antigenic (column 1, lines 41-46). Ronan et al. teach that in addition to the silver ions having effective antiseptic characteristics, that the heavy metal of silver has inherent radiopaque characteristics. In view of Yamamoto, as evidenced by Ronan et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to bind a radiographically detectable metallic ion to the bioabsorbable material of Fulton, III et al. to cause silver ions to be chelated to functional groups in the collagen, thus further protecting against bacterial and fungal attack in addition to the inherent radiopaque characteristics of the silver ions.

Regarding claims 78 and 80, Fulton, III et al. note, in column 6, lines 57-63, that a gelatin (line 63) may be substituted for the collagen material. Fulton, III et al. further teach the bioabsorbable material being dehydrated (Abstract; column 2, lines 28-29).

Regarding claims 81-84 although the cited prior art does not disclose the specific Bloom rating of the body, the body of the cited prior art is nonetheless within the claimed Bloom rating range to achieve implantation (i.e., the body must possess the requisite degree of softness, but also a certain amount of firmness to facilitate implantation).

19. Claims 111 and 112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al. (U.S. Patent No. 6,228,055) in view of Voegele et al. (U.S. Patent No. 6,261,302) and Fulton, III et al. (U.S. Patent No. 6,270,464) as applied to claims 68, 69, 71, 113, 114 and 116 above, and further in view of Li (U.S. Patent No. 6,350,274).

Foerster et al. in view of Voegele et al. and Fulton, III et al. discloses all of claimed limitations, as previously set forth, except for specifically calling for the at least one shaped solid preshaped marker being formed of a bioabsorbable material having widths of 1 to 3 mm and lengths of 5 to 10 mm.

However, a bioabsorbable separate solid marker body having a width of 1 to 3 mm and a length of about 5 to 10 mm is known in the art. Li, for example, teaches a resorbable implant member (13) in which the member is made by pouring a collagen, etc. matrix into molds in which the diameter (i.e. width) of the mold is preferably in the range of about ***3 mm*** to about 15 mm and the length (i.e. height) of the mold is preferably in the range of about ***5 mm*** to about 25 mm (complete range of about 5mm to 10mm). Li further teaches that such a configuration provides a means to obtain the optimum material for further processing (column 8, lines 27-39).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the silent size of Foerster et al. in view of at least Fulton, III et al. with the bioabsorbable separate solid marker body having a width of 1 to 3 mm and a length of about 5 to 10 mm of Li in order to provide a means to obtain the optimum material for further processing. Similarly, the examiner asserts use of known technique to improve similar devices in the same way is obvious to one of ordinary skill in the art. That is, the manner of enhancing a particular device (providing a bioabsorbable separate solid marker body having a width of 1 to 3 mm and a length of about 5 to 10 mm) was made part of the ordinary capabilities of one skilled in the art based upon the teaching of such improvement in Li. Accordingly, one of ordinary skill in the art would have been capable of applying this known “improvement” technique in the same manner to the prior art system for delivering a plurality of maker bodies to a biopsy cavity of predetermined size of Foerster et al. in view of at least Fulton, III et al. and the results would have been predictable to one of ordinary skill in the art, namely, one skilled in the art would have readily recognized that providing a bioabsorbable separate solid marker body having a width of 1 to 3 mm and a length of about 5 to 10 mm in Foerster et al. in view of at least Fulton, III et al. would positively provide a means to obtain the optimum material for further processing.

Furthermore, the examiner asserts that choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success (i.e. “Obvious to try”) is obvious to one of ordinary skill in the art. That is Li explicitly teaches providing a bioabsorbable separate solid marker body having a width of 1 to 3 mm and a length of about 5 to 10 mm. Therefore with the teaching of Li utilizing a bioabsorbable separate solid marker body having a width of 1 to 3 mm and a length of about 5 to 10 mm, Li teach that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success (i.e. Obvious to try).

It would have also been obvious to one of ordinary skill in the art at the time of the invention was made to make the width 1 to 3 mm and the length 5 to 10 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

20. Claim 115 is rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al. (U.S. Patent No. 6,228,055) in view of Voegele et al. (U.S. Patent No. 6,261,302) and Fulton, III et al. (U.S. Patent No. 6,270,464) as applied to claims 68, 69, 71, 113, 114 and 116 above, and further in view of Ronan (U.S. Patent No. 5,820,918).

Foerster et al. in view of Voegele et al. and Fulton, III et al. discloses all of claimed limitations, as previously set forth, except for specifically calling for the bioabsorbable material having a solubility coefficient of less than 1 x $10^{-3}$ grams per 100 cc of water.

However, a bioabsorbable material having a solubility coefficient of less than 1 x $10^{-3}$ grams per 100 cc of water is known in the art. Ronan, for example, teaches the use of additives silver chloride (AgCl) and barium sulfate ($BaSO_4$) having relatively low water solubility to prevent them form being rapidly washed away by bodily fluids (column 1, lines 39-49). In addition, the examiner asserts that silver chloride (AgCl) and barium sulfate ($BaSO_4$) have a solubility coefficient of less than 1 x $10^{-3}$ grams per 100 cc of water as is evidenced by applicant's disclosure (U.S. Patent No. 6,161,034, column 11, line 56 – column 12, line 19). Furthermore, if a composition is physically the same (silver chloride – AgCl; and barium sulfate – $BaSO_4$), it must have the same properties. A chemical composition and its properties are inseparable. Consequently since the prior art teaches the same chemical composition (silver chloride – AgCl; and barium sulfate – $BaSO_4$), the properties of instant claims are necessarily present. See In re Spada, 15 USPQ 2d 1655, 1658. Therefore, silver chloride (AgCl) and barium sulfate ($BaSO_4$) are deemed to have a solubility coefficient of less than 1 x $10^{-3}$ grams per 100 cc of water. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the bioabsorbable material of Foerster et al. in view of at least Fulton, III et al. with the bioabsorbable material having a solubility coefficient of less than 1 x $10^{-3}$ grams per 100 cc of water of Ronan in order to prevent them form being rapidly washed away by bodily fluids.

21. Claims 68, 69, 71, 73-75, 85, 86, 113, 114 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al. (U.S. Patent No. 6,228,055) in view of Voegele et al. (U.S. Patent No. 6,261,302) and Sirimanne et al. (U.S. Patent No. 6,356,752).

Foerster et al. disclose, in Figures 12-15, a delivery cannula defined at least in part by an inner wall surface (inner surface of tube 54b) for implanting biopsy site markers that ejects biopsy markers from the cannula into the desired tissue without the need to push the distal end of the cannula out from the lateral biopsy window. In addition, Foerster et al. disclose a plunger (mandrel 98e) which is slidable in the inner lumen (see Figure 15) proximal to at least one solid marker body and detached from the at least one solid marker body (12e). Such a feature utilizes compressive forces rather than tensile forces for delivery (column 10, lines 5-12). Moreover, as noted in column 10, lines 5-11 and column 13, lines 16-29, the device can eject multiple markers individually in series.

In addition, Forester et al. disclose a plurality of marker bodies (12b; two elements) preloaded in the tube (54a) (column 10, lines 5-11) to provide an arrangement enabling implanting an array of markers with a single cannula without reloading, thus enabling implantation at multiple biopsy sites (column 11, lines 8-15). In addition, Forester et al. teach at least five markers can be *inserted simultaneously*, thereby permitting the deployment of more markers without having to pause and disengage to re-load (12e; five elements; column 12, line 1-5; see Figure 15). Furthermore, Forester et al. teach marker elements/bodies may be small beads/pellets (12i) (column 13, lines 16-29; see Figure 12i).

Foerster et al. disclose all of the limitations of the claimed invention, as previously set forth, except for a ramp within the cannula inclined to the elongated discharge port and the plunger urging the plurality of marker bodies into engagement with the ramp and slidably move the plurality of marker bodies up the ramp and out of the discharge port in the delivery cannula into the biopsy cavity; at least one body being ultrasonically detectable and at least one other of the marker bodies being radiographically detectable; the marker body being solid at a temperature of 40º C; and at least one marker body having a colorant incorporated therein.

However, a ramp within the cannula of a biopsy marker delivery tool configured to urge a marker body out of the discharge port into the biopsy cavity, as described by Voegele et al., is known in the art. Voegele et al., for example, teach an applier (30) for delivering and deploying a biopsy marker to a biopsy site. In addition, Voegele et al. teach the applier (30) comprising an egress tube (63) having an egress opening (64) further having an egress ramp (65) (column 8, line 65 – column 9, line 2; see Figures 1, 2, 5, 7, 8, 13, 17, 18, 19). Voegele et al. further teach the advantage of such a configuration provides for proper delivery and placement at the biopsy site (column 9, line 63 – column 10, line 4; see Figures 20-28). Furthermore it is noted that such a configuration provides that ability to eject the marker cannula for implantation in the tissue in a direction substantially perpendicular to the longitudinal movement of the ejector, thereby increasing the accuracy and placement of the marker into the biopsy site.

Similarly, a marker device being a bioabsorbable marker with radiographically detectable marker having a radiopaque member that may be disposed inside of the marker body having a loop and at least one free end and being made of a material selected from a group consisting of titanium; stainless steel, tantalum, gold, platinum and palladium is known in the art. Sirimanne et al., for example, teach a expandable/swellable bioabsorbable body contained within the elongate tubular member (marking device 402 made of expanding gelatinous bioabsorbable materials; column 8, lines 1-9), the bioabsorbable body comprising gelatin (column 8, lines 1-42); and a radiographically detectable interior (144) being filled with a solid or gelatinous material that can be optionally made radiopaque (column 7, lines 48-53; column 8, lines 31-42) or a marker contained carried within the bioresorbable body(s) (marker 110 in the form of 150-156; column 8, lines 1-61).

Sirimanne et al. further teach at least one marker body being slidably disposed within the inner lumen see Figures 4A-4L); at least one bioresorbable body is remotely visualizable by at least one of ultrasound and mammography (Abstract); the radiographically detectable marker is radiopaque (column 3, lines 55-58). Sirimanne et al. also teach the biopsy site being relocated by detecting the radiographically detectable marker with mammography or ultrasound (column 9, lines 40-44; column 10, lines 8-14) and the marker elements being echogenic and/or radiopaque (column 7, lines 55-67; column 8, lines 31-41; column 10, lines 1-13). Therefore, Sirimanne et al. fully meets “wherein at least one marker body is being ultrasonically detectable and at least one other of the marker bodies being radiographically detectable” given its broadest reasonable interpretation.

In addition, Sirimanne et al., teach a bioabsorbable body (104) containing a radiopaque member (150, 154; see Figures 1A-1D, 1F, 2A-2F, 3C,3D) in which the radiopaque member may be made of a material made of selected from a group consisting of titanium; stainless steel, tantalum, gold, platinum and palladium (column 9, lines 29-43).

Sirimanne et al. further teach the advantage of such a configuration provides a means to aid a physician to determine the spatial orientation of the deployed device (column 2, lines 14-51; column 6, lines 47-50).

In view of Voegele et al., it would have been obvious to one of ordinary skill in the art at the time of the invention was made to provide a ramp within the cannula inclined to a distal portion of the elongated discharge port and urge a marker body out of the discharge port into the biopsy cavity to allow for proper delivery and placement at the biopsy site and to provide a ramp within the cannula inclined to a distal portion of the elongated discharge port and urge a marker body out of the discharge port into the biopsy cavity and to provide a mechanism to eject the marker cannula for implantation in the tissue in a direction substantially perpendicular to the longitudinal movement of the ejector, thereby increasing the accuracy and placement of the marker into the biopsy site. Similarly, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the radiographically bioabsorbable marker body of Foerster et al. with the bioabsorbable material marker having radiopaque member therein of Sirimanne et al. in order to provide a means to aid a physician to determine the spatial orientation of the deployed device, thereby increasing the operational efficiency of the marker bodies.

Regarding claim 69, the cited prior art does not expressly disclose the body's ability to remain solid at 40º C. However, not only is such a feature implied by the prior art to ensure the marker remained intact after implantation (i.e., upon exposure to body temperature), the skilled artisan would know to select such a body because the marker is intended to be implanted into the patient and therefore must remain solid at temperatures several degrees above body temperature. Therefore, it would have been obvious to one of ordinary skill in the art to provide a body that is solid at 40º C in the previously described apparatus to ensure the marker remained intact after implantation.

22. Claims 76-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al. (U.S. Patent No. 6,228,055) in view of Voegele et al. (U.S. Patent No. 6,261,302) and Sirimanne et al. (U.S. Patent No. 6,356,752) as applied to claims 68, 69, 71, 73-75, 85, 86, 113, 114 and 116 above, and further in view of Yamamoto (U.S. Patent No. 4,847,049), as evidenced by Ronan et al. (U.S. Patent No. 5,820,918).

Foerster et al. in view of Voegele et al. and Sirimanne et al. discloses all of the claimed limitations, as previously set forth, except for specifically calling for at least one of the bodies being formed of a cross-linked bioabsorbable material and having a radiographically detectable metallic ion bound to the cross-linked bioabsorbable material.

However, binding metallic ions to collagens in medical devices used in contact with bodily fluids and tissues is well known in the art to protect against bacterial and fungal attack. Yamamoto, for example, discloses contacting a renatured, cross-linked collagen with silver ion-containing solution with a PH from 4.0-9.0 to cause silver ions to be chelated to functional groups in the renatured collagen. The silver-chelated collagen is then exposed to UV radiation at a 210-310 nm wavelength for 5-15 minutes (column 4, lines 23-24) to strengthen the binding of the silver ions to the renatured collagen (column 2, lines 7-19 and 60-68). Yamamoto further teaches the use of renatured collagen instead of naturally occurring collagen to provide a collagen material that is less antigenic (column 1, lines 41-46). Ronan et al. teach that in addition to the silver ions having effective antiseptic characteristics, that the heavy metal of silver has inherent radiopaque characteristics. In view of Yamamoto, as evidenced by Ronan et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to bind a radiographically detectable metallic ion to the bioabsorbable material of Sirimanne et al. to cause silver ions to be chelated to functional groups in the collagen, thus further protecting against bacterial and fungal attack in addition to the inherent radiopaque characteristics of the silver ions.

Regarding claims 78 and 80, Sirimanne et al. note, in column 6, lines 57-63, that a gelatin (line 63) may be substituted for the collagen material.

Regarding claims 81-84 although the cited prior art does not disclose the specific Bloom rating of the body, the body of the cited prior art is nonetheless within the claimed Bloom rating range to achieve implantation (i.e., the body must possess the requisite degree of softness, but also a certain amount of firmness to facilitate implantation).

23. Claims 111 and 112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al. (U.S. Patent No. 6,228,055) in view of Voegele et al. (U.S. Patent No. 6,261,302) and Sirimanne et al. (U.S. Patent No. 6,356,752) as applied to claims 68, 69, 71, 73-75, 85, 86, 113, 114 and 116 above, and further in view of Li (U.S. Patent No. 6,350,274).

Foerster et al. in view of Voegele et al. and Sirimanne et al. discloses all of claimed limitations, as previously set forth, except for specifically calling for the at least one shaped solid preshaped marker being formed of a bioabsorbable material having widths of 1 to 3 mm and lengths of 5 to 10 mm.

However, a bioabsorbable separate solid marker body having a width of 1 to 3 mm and a length of about 5 to 10 mm is known in the art. Li, for example, teaches a resorbable implant member (13) in which the member is made by pouring a collagen, etc. matrix into molds in which the diameter (i.e. width) of the mold is preferably in the range of about ***3 mm*** to about 15 mm and the length (i.e. height) of the mold is preferably in the range of about ***5 mm*** to about 25 mm (complete range of about 5mm to 10mm). Li further teaches that such a configuration provides a means to obtain the optimum material for further processing (column 8, lines 27-39).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the silent size of Foerster et al. in view of at least Sirimanne et al. with the bioabsorbable separate solid marker body having a width of 1 to 3 mm and a length of about 5 to 10 mm of Li in order to provide a means to obtain the optimum material for further processing. Similarly, the examiner asserts use of known technique to improve similar devices in the same way is obvious to one of ordinary skill in the art. That is, the manner of enhancing a particular device (providing a bioabsorbable separate solid marker body having a width of 1 to 3 mm and a length of about 5 to 10 mm) was made part of the ordinary capabilities of one skilled in the art based upon the teaching of such improvement in Li. Accordingly, one of ordinary skill in the art would have been capable of applying this known “improvement” technique in the same manner to the prior art system for delivering a plurality of maker bodies to a biopsy cavity of predetermined size of Foerster et al. in view of at least Sirimanne et al. and the results would have been predictable to one of ordinary skill in the art, namely, one skilled in the art would have readily recognized that providing a bioabsorbable separate solid marker body having a width of 1 to 3 mm and a length of about 5 to 10 mm in Foerster et al. in view of at least Fulton, III et al. would positively provide a means to obtain the optimum material for further processing.

Furthermore, the examiner asserts that choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success (i.e. “Obvious to try”) is obvious to one of ordinary skill in the art. That is Li explicitly teaches providing a bioabsorbable separate solid marker body having a width of 1 to 3 mm and a length of about 5 to 10 mm. Therefore with the teaching of Li utilizing a bioabsorbable separate solid marker body having a width of 1 to 3 mm and a length of about 5 to 10 mm, Li teach that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success (i.e. Obvious to try).

It would have also been obvious to one of ordinary skill in the art at the time of the invention was made to make the width 1 to 3 mm and the length 5 to 10 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

24. Claim 115 is rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al. (U.S. Patent No. 6,228,055) in view of Voegele et al. (U.S. Patent No. 6,261,302) and Sirimanne et al. (U.S. Patent No. 6,356,752) as applied to claims 68, 69, 71, 73-75, 85, 86, 113, 114 and 116 above, and further in view of Ronan (U.S. Patent No. 5,820,918).

Foerster et al. in view of Voegele et al. and Sirimanne et al. discloses all of claimed limitations, as previously set forth, except for specifically calling for the bioabsorbable material having a solubility coefficient of less than $1 \times 10^{-3}$ grams per 100 cc of water.

However, a bioabsorbable material having a solubility coefficient of less than $1 \times 10^{-3}$ grams per 100 cc of water is known in the art. Ronan, for example, teaches the use of additives silver chloride (AgCl) and barium sulfate ($BaSO_4$) having relatively low water solubility to prevent them form being rapidly washed away by bodily fluids (column 1, lines 39-49). In addition, the examiner asserts that silver chloride (AgCl) and barium sulfate ($BaSO_4$) have a solubility coefficient of less than $1 \times 10^{-3}$ grams per 100 cc of water as is evidenced by applicant's disclosure (U.S. Patent No. 6,161,034, column 11, line 56 – column 12, line 19). Furthermore, if a composition is physically the same (silver chloride – AgCl; and barium sulfate – $BaSO_4$), it must have the same properties. A chemical composition and its properties are inseparable. Consequently since the prior art teaches the same chemical composition (silver chloride – AgCl; and barium sulfate – $BaSO_4$), the properties of instant claims are necessarily present. See In re Spada, 15 USPQ 2d 1655, 1658. Therefore, silver chloride (AgCl) and barium sulfate ($BaSO_4$) are deemed to have a solubility coefficient of less than $1 \times 10^{-3}$ grams per 100 cc of water. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the bioabsorbable material of Foerster et al. in view of at least Sirimanne et al. with the bioabsorbable material having a solubility coefficient of less than $1 \times 10^{-3}$ grams per 100 cc of water of Ronan in order to prevent them form being rapidly washed away by bodily fluids.

## ***Remarks***

25. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In that regard, Foerster et al. explicitly disclose a plunger (mandrel 98e) which is slidably disposed in part within the inner lumen (tube 54e) of the delivery cannula proximal to the at least one solid marker body (12b, 12e; see Figures 12, 15) and detached from the at least one solid marker body(12b, 12e; see Figures 12, 15), the plunger (mandrel 98e) having and which has a distal end configured to slidably engage and advance… (see Figures 12, 15). Therefore, Forester et al. fully meets "a plunger which is slidably disposed in part within the inner lumen of the delivery cannula proximal to the at least one solid marker body and detached from the at least one solid marker body, the plunger having and which has a distal end configured to slidably engage and advance…" given its broadest reasonable interpretation.

In addition, Voegele et al teach an applier (30) for delivering and deploying a biopsy marker to a biopsy site. In addition, Voegele et al. teach the applier (30) comprising an egress tube (63) having an egress opening (64) further having an egress ramp (65) (column 8, line 65 – column 9, line 2; see Figures 1, 2, 5, 7, 8, 13, 17, 18, 19). Voegele et al. further teach the advantage of such a configuration provides for proper delivery and placement at the biopsy site (column 9, line 63 – column 10, line 4; see

Figures 20-28). Furthermore, the examiner asserts such a configuration provides the ability to eject the marker cannula for implantation in the tissue in a direction substantially perpendicular to the longitudinal movement of the ejector, thereby increasing the accuracy and placement of the marker into the biopsy site.

Therefore since Foerster et al. discloses a plunger (mandrel 98e) which is slidably disposed in part within the inner lumen (tube 54e) of the delivery cannula proximal to the at least one solid marker body (12b, 12e; see Figures 12, 15) and detached from the at least one solid marker body(12b, 12e; see Figures 12, 15), the plunger (mandrel 98e) having and which has a distal end configured to slidably engage and advance… and Voegele et al. teach the applier (30) comprising an egress tube (63) having an egress opening (64) further having an egress ramp (65) (column 8, line 65 – column 9, line 2; see Figures 1, 2, 5, 7, 8, 13, 17, 18, 19), Foerster et al. in view of Voegele et al. fully meets "a plunger which is slidably disposed in part within the inner lumen of the delivery cannula proximal to the at least one solid marker body and detached from the at least one solid marker body, the plunger having a distal end configured to slidably engage and advance the at least one solid marker body from the location proximal to elongated discharge port into engagement with the ramp and slidably move the at least one solid marker body up the ramp and out of the discharge port in the delivery cannula into the biopsy cavity" given its broadest reasonable interpretation.

26. With respect to appellant's reply/argument that the combination provides no *prima facie* case of obviousness, the examiner respectfully disagrees. The examiner

has provided primary reference (i.e. Foerster et al.) and asserted to applicant which limitations to which the primary reference reads on. In addition, examiner has provided applicant with what the primary reference is lacking, as set forth above. The examiner further provides reference to Voegele et al. for the providing a ramp in a distal end of a biopsy delivery tool for object delivery. Voegele et al. further explicitly teach the advantage of providing for proper delivery and placement at the biopsy site. Furthermore the examiner asserted that such a configuration provides the ability to eject the marker cannula for implantation in the tissue in a direction substantially perpendicular to the longitudinal movement of the ejector, thereby increasing the accuracy and placement of the marker into the biopsy site.

To establish a *prima facie* case of obviousness, the examiner has provided at least the exemplary rationales to support a conclusion of obviousness in: “applying a known technique to a known device ready for improvement to yield predictable results”; “Use of known technique to improve similar devices (methods, or products) in the same way would yield predictable results”; and “some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention (see MPEP § 2143). Therefore, the examiner maintains Voegele et al., when combined with Foerster et al., establishes a *prima facie* case of obviousness.

First, the examiner asserts that applying a known technique to a known device ready for improvement would yield predictable results. That is, it would have been recognized by one of ordinary skill in the art that applying the known technique taught by Voegele et al. to the system of Foerster et al. would have yielded predicable results and resulted in an improved system, namely, providing a ramp in a distal end of a biopsy delivery tool for object delivery in Foerster et al. to provide proper delivery and placement at the biopsy site as well as provide the ability to eject the marker cannula for implantation in the tissue in a direction substantially perpendicular to the longitudinal movement of the ejector, thereby increasing the accuracy and placement of the marker into the biopsy site.

Similarly, the examiner asserts use of known technique to improve similar devices in the same way is obvious to one of ordinary skill in the art. That is, the manner of enhancing a particular device (providing a ramp in a distal end of a biopsy delivery tool for object delivery) was made part of the ordinary capabilities of one skilled in the art based upon the teaching of such improvement in Voegele et al. Accordingly, one of ordinary skill in the art would have been capable of applying this known “improvement” technique in the same manner to the prior art system of Foerster et al. and the results would have been predictable to one of ordinary skill in the art, namely, one skilled in the art would have readily recognized that providing a ramp in a distal end of a biopsy delivery tool for object delivery in Foerster et al. would positively provide proper delivery and placement at the biopsy site as well as provide the ability to eject the marker cannula for implantation in the tissue in a direction substantially perpendicular to the longitudinal movement of the ejector, thereby increasing the accuracy and placement of the marker into the biopsy site.

And moreover, the examiner asserts a prior art teaching and suggest would have led one of ordinary skill to modify the prior art reference or to combine prior art. That is Voegele et al. specifically teach that providing a ramp in a distal end of a biopsy delivery tool for object delivery presents a means to proper delivery and placement at the biopsy site as well as provide the ability to eject the marker cannula for implantation in the tissue in a direction substantially perpendicular to the longitudinal movement of the ejector, thereby increasing the accuracy and placement of the marker into the biopsy site.

Therefore, since the examiner has established a *prima facie* case of obviousness as set forth in MPEP § 2143, the rejection of Foerster et al. in view of at least Voegele et al. stands.

27. In response to applicant's argument that combination of Foerster et al. in view of Voegele et a. and Futon, III et al. would not yield the structure of the present invention or render it obvious, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

28. Applicant has cited several court cases. One of them, KSR, in fact, supports the examiner's position, not applicant's, as set forth by the Court. With respect to the others the fact scenarios are different and are, therefore, not applicable.

29. With respect to applicant’s reply/argument to claims 81-84 and the Bloom Strength, the examiner asserted that the particular Bloom strength was not specifically disclosed. However, the examiner asserted that the body of the prior art (i.e. Fulton, III et al./Sirimanne et al.) is nonetheless within the claimed Bloom rating to achieve implantation (i.e. the body must possess the requisite degree of softness, but also a certain amount of firmness to facilitate implantation). Applicant discloses a Bloom rating of 75 being like food gelatin and a Bloom rating of 300 being like a soft rubber eraser (page 11, lines 21-29). Fulton, III et al. teach the plug (34) being dehydrated collagen as well as the plug being at least 1.5 times harder typically than breast tissue in order to be palpable (column 5, lines 3-21). Clearly the dehydrated collagen is not like food gelatin and closer to a soft rubber eraser and the after delivery-harder palpable element being at least 1.5 times harder than breast tissue is harder than food gelatin and again in the range of a soft rubber eraser. Therefore, the examiner deems bioabsorbable plug (34) to fully meet the Bloom strength as recited by applicant as evidenced by applicant's disclosure of Bloom strength comparisons as well as the teachings of Fulton, III et al. Similarly, Sirimanne et al. teach the interior being filled with a solid or gelatinous material... (column 8, lines 51-54; column 8, lines 1-6), preferably a spongy collagen (column 8, line 16). Clearly the spongy collagen is not like food gelatin and closer to a soft rubber eraser as well. Therefore, the examiner deems interior (144) to fully meet the Bloom strength as recited by applicant as evidenced by applicant's disclosure of Bloom strength comparisons as well as the teachings of Sirimanne et al.

30. With respect to applicant's reply/argument to Li, the examiner respectfully asserts that Li fully meets "a bioabsorbable separate solid marker body having a width of 1 to 3 mm and a length of about 5 to 10 mm" since numbers of the recited range are taught by Li in order to provide a means to obtain the optimum material for further processing. Similarly, the examiner asserts use of known technique to improve similar devices in the same way is obvious to one of ordinary skill in the art. That is, the manner of enhancing a particular device (providing a bioabsorbable separate solid marker body having a width of 1 to 3 mm and a length of about 5 to 10 mm) was made part of the ordinary capabilities of one skilled in the art based upon the teaching of such improvement in Li. Accordingly, one of ordinary skill in the art would have been capable of applying this known "improvement" technique in the same manner to the prior art system for delivering a plurality of maker bodies to a biopsy cavity of predetermined size of Foerster et al. in view of at least Sirimanne et al. and the results would have been predictable to one of ordinary skill in the art, namely, one skilled in the art would have readily recognized that providing a bioabsorbable separate solid marker body having a width of 1 to 3 mm and a length of about 5 to 10 mm in Foerster et al. in view of at least Fulton, III et al. would positively provide a means to obtain the optimum material for further processing.

Moreover, the examiner asserts that choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success (i.e. "Obvious to try") is obvious to one of ordinary skill in the art. That is Li explicitly teaches providing a bioabsorbable separate solid marker body having a width of 1 to 3 mm and a length of about 5 to 10 mm. Therefore with the teaching of Li utilizing a bioabsorbable separate solid marker body having a width of 1 to 3 mm and a length of about 5 to 10 mm, Li teach that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success (i.e. Obvious to try).

And furthermore, it would have also been obvious to one of ordinary skill in the art at the time of the invention was made to make the width 1 to 3 mm and the length 5 to 10 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Therefore, since the examiner has established a *prima facie* case of obviousness as set forth in MPEP § 2143, the rejection of Foerster et al. in view of at least Voegele et al., Fulton, III et al./Sirimanne et al. and Li stands.

## ***Prior Art***

31. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Publication No. 2006/0122503 to Burbank et al. is a teaching of an imageable biopsy site.

U.S. Publication No. 2006/0155190 to Burbank et al. is a teaching of an imageable biopsy site marker.

## *Conclusion*

32. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEPHEN J. RALIS whose telephone number is (571)272-6227. The examiner can normally be reached on Monday - Friday, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tu Hoang can be reached on 571-272-4780. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephen J Ralis/
Primary Examiner, Art Unit 3742

Stephen J Ralis
Primary Examiner
Art Unit 3742

SJR
November 19, 2010